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Allen Lubow

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EXAMINER

NGUYEN, HIEP VAN

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/511,864	Applicant(s) LUBOW, ALLEN	
	Examiner HIEP NGUYEN	Art Unit 3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☒ Claim(s) 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/03/2007, 03/07/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-27 have been examined.

Claim Objections

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

One of Two Claims for number 12 has been misnumbered. One of these two claims depends from Claim 10, other depends from Claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 21-27 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

5. Claim 21 is directed to a method of producing a foldable and sealable packet.

Claim 21 recites storing electronic patient information, medication, and database.

However, this is merely software, and it has been held that software without a required

computer-readable medium-storing the software that, when executed, causes the computer to perform a particular process or method (MPEP 2106.01) is merely nonfunctional descriptive material and non-statutory under 35 U.S.C. 101.

Claims 22-25 are rejected as each depends from claim 21.

6. Claim 26 is directed to a method of dispensing medication. Claim 26 recites printing a foldable packet dispensing medication. However, this is merely software, and it has been held that software without a required computer-readable medium-storing the software that, when executed, causes the computer to perform a particular process or method (MPEP 2106.01) is merely nonfunctional descriptive material and non-statutory under 35 U.S.C. 101.

Claim 27 is rejected as it depends from Claim 26.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 9, 12, 14, 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9, 12, 14, 15 contain the trademark/trade name RSS/CS barcode. Where a trademark or trade name is used in a claim as a limitation to identify or describe a

particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a particular brand name of barcode device and, accordingly, the identification/description is indefinite.

9. Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-20, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue et al. (US PGPub. 20030102247) in view of Chorosinski et al. (US. 5,945,651.)

12. With respect to Claim 1, Inoue et al. teaches a foldable and sealable packet, the packet comprising:

folding perforations on the packet to define locations for folding ('247; Para 0049);

a sealant, wherein the sealant maintains the shape of the packet after the packet is folded at the folding perforations, wherein after the packet is folded and at least partially sealed, the packet is formed to become a container to receive the contents ('247; Paras 0053; 0069.)

Inoue et al. only discloses the covering sheet provided with a printed layer formed by printing ink for contents of the package ('247; Para 0108). However Inoue et al. does not disclose a bar code on the packet which contains information directed at least to contents of the packets.

Chorosinski et al. discloses further a bar code on the packet, the bar code containing information directed at least to contents of the packet ('651; Col. 5, lines 3-17.)

Therefore it would have been obvious to one of ordinary skilled in the art at the time of invention was made to combine Inoue et al. relating to a packet containing a tablet and Chorosinski et al. relating to description of said barcode label affixed on medication packet.

13. With respect to Claim 2, the combined art teaches the foldable and sealable packet of claim 1, Inoue et al. discloses further wherein the contents include at least one of medication and hardware ('247; Para 0045-0046.)

14. With respect to Claim 3, the combined art teaches the foldable and sealable packet of claim 2, Inoue et al. discloses further wherein the medication includes at least one of capsules, tablets, gelcaps, dissolving strips, and caplets ('247; Paras 0045-0046.)

15. With respect to Claim 4, the combined art teaches the foldable and sealable packet of claim 1, Inoue et al. discloses further comprising human readable information printed on the packet ('247; Para 0108.)

16. With respect to Claim 5, the combined art teaches the foldable and sealable packet of claim 4, Chorosinski et al. discloses wherein the human readable information directed to at least one of a patient who is intended to receive the packet, the contents of the packet, and instructions for opening the packet ('651; Col. 5, lines 3-17; fig. 2B: name of patient with medication information, barcode.)

17. With respect to Claim 6, the combined art teaches the foldable and sealable packet of claim 1, Chorosinski et al. discloses further comprising an image that represents the contents of the packet ('651; Fig 2B: image of pills /tablets).

18. With respect to Claim 7, the combined art teaches the foldable and sealable packet of claim 1, Inoue et al. discloses further comprising a polycoat portion ('247; Para. 0072-0073.)

19. With respect to Claim 8, the combined art teaches the foldable and sealable packet of claim 1, Inoue et al. discloses further comprising a tear off perforation portion enabling the removal of individual foldable and sealable packets in a strip of foldable and sealable packets ('247; Fig. 3 incision and perforation.)

20. With respect to Claim 9, the combined art does not disclose, wherein the bar code is a RSS/CS barcode. However, Official Notice is taken that the RSS/CS barcode has been well known as a basis for labeling barcoded information on a packet. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Inoue et al. / Chorosinski et al. to utilize the RSS/CS barcode on a medication packet.

21. With respect to Claim 10, the combined art teaches the foldable and sealable packet of claim 1, Inoue et al. discloses wherein the packet comprises blister packs ('247; Para 0008.)

22. With respect to Claim 11, the combined art teaches the foldable and sealable packet of claim 10, Inoue et al. discloses wherein the blister packs are formed with at least one of a paper and film portion having an ink layer disposed thereon, and wherein the ink layer is adapted to be removed by a laser ('247; Para. 0095).

23. With respect to Claim 12, the combined art teaches the foldable and sealable packet of claim 10, Inoue et al. discloses further comprising a bar code formed in the at least one of paper and film by the removal of the ink by the laser ('247; Para. 0094-0095.)

24. With respect to Claim 12, the combined art teaches the foldable and sealable packet of claim 1, Inoue et al. discloses wherein a first of a plurality foldable and sealable packets comprises information regarding the remaining ones of the foldable and sealable packets in the strip ('247; Para. 0094-0095.)

25. With respect to Claim 13, the combined art teaches the foldable and sealable packet of claim 1, Inoue et al. discloses further comprising a removable tab portion ('247; Para 0110.)

26. With respect to Claim 14, the combined art teaches the foldable and sealable packet of claim 13, Chorosinski et al. discloses wherein the removable tab portion

comprises a CS portion of a bar code and a part of a linear portion of the barcode, and the portion of the foldable and sealable packet adjacent to the tab portion comprises another substantially identical CS portion and another part of the linear portion ('651; Fig. 2B barcode expansion to the edge of perforation.)

27. With respect to Claim 15, the combined art teaches the foldable and sealable packet of claim 14, Chorosinski et al. discloses wherein the removable tab, when removed, comprises a copy of the barcode on the portion of the foldable and sealable packet of claim adjacent to the tab portion ('651; Fig. 2B barcode expansion to the edge of perforation).

28. With respect to Claim 16, the combined art teaches the foldable and sealable packet of claim 1, Inoue et al. discloses further comprising an at least partially transparent window that enables a person to see the contents of the foldable and sealable packet ('247; Para 0050: Fig 3 and covering sheet to be transparent.)

29. With respect to Claim 17, the combined art teaches the foldable and sealable packet of claim 1, Inoue et al. discloses further comprising a plurality of foldable and sealable packets formed in a web of a roll of foldable and sealable packets ('247; fig 12;; Para 0157.)

30. With respect to Claim 18, the combined art teaches the foldable and sealable packet of claim 1, Chorosinski et al. discloses further comprising at least one shape printed on the foldable and sealable packet, wherein the shape represents information directed to at least one of the contents of the foldable and sealable packet and the person who receives the foldable and sealable packet ('651; Col. 7, lines 1-44.)

31. With respect to Claim 19, the combined art teaches the foldable and sealable packet of claim 18, Inoue et al. discloses wherein the at least one shape is formed as at least one of a polygon, a bar, and a circle ('247; Para 0047, 0067).

32. With respect to Claim 20, the combined art teaches the foldable and sealable packet of claim 18, Chorosinski et al. discloses wherein the information regards at least one dosage, frequency of use, time of day for ingestion and warnings directed to the contents of the foldable and sealable packet ('651; Col. 5, lines 3-17.)

33. With respect to Claim 28, the combined art teaches the method of claim 14, Chorosinski et al. discloses wherein the bars of the linear portion extend continuously from the foldable and sealable packet to the removable tab portion ('651; Fig. 2B.)

34. Claims 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue et al. (US PGPub. 20030102247) in view of Chorosinski et al. (US. 5,945,651), and further in view of Walsh (US. 6,464,136.)

35. With respect to Claim 21, Inoue et al. teaches a method for producing a foldable and sealable packet, the method comprising:

dispensing at least one medication in the foldable and sealable packet ('247; Para 0045-0046);

folding and sealing the foldable and sealable packet such that the packet becomes a container for the at least one medication ('247; Paras 0048-0049.)

Inoue et al. only discloses the covering sheet provided with a printed layer formed by printing ink for contents of the package ('247; Para. 0108). However Inoue et al. does not disclose a bar code on the packet which contains information directed at least to contents of the packets.

Chorosinski et al. discloses printing at least a bar code on the foldable and sealable packet ('651; Col. 5, lines 3-17);

Therefore it would have been obvious to one of ordinary skilled in the art at the time of invention was made to combine Inoue et al. relating to a packet containing a tablet and Chorosinski et al. relating to description of said barcode label affixed on medication packet.

However, the combined art Inoue et al./Chorosinski et al. does not disclose:

storing electronic patient information in a database, the electronic patient information representing at least a patient;

storing electronic medication information in at least one of the database and another database, the electronic medication information representing information regarding at least one of a plurality of medications;

providing at least one of the electronic patient information and the electronic medication information to a patient caregiver;

receiving electronic instructions from the patient caregiver, the electronic instructions comprising instructions directed to medication for the patient.

Walsh discloses:

storing electronic patient information in a database, the electronic patient information representing at least a patient ('136; Col./line 24/66-25/5);

storing electronic medication information in at least one of the database and another database, the electronic medication information representing information regarding at least one of a plurality of medications ('136, Col. 26, lines 28-32);

providing at least one of the electronic patient information and the electronic medication information to a patient caregiver, and receiving electronic instructions from the patient caregiver, the electronic instructions ('136, Col. 26, lines 21-27.)

Therefore it would have been obvious to one of ordinary skilled in the art at the time of invention was made to modify the teachings of Inoue et al./ Chorosinski et al.

relating to a packet with barcode label and the teachings of Walsh relating to database of patient medication.

36. With respect to Claim 22, the combined art teaches the method of claim 21, Chorosinski et al. discloses further comprising referencing at least one Internet web page to discover information directed to the at least one medication ('651; Col. 7, lines 10-44.)

37. With respect to Claim 23, the combined art teaches the method of claim 21, Walsh discloses wherein the step of receiving electronic instructions comprises receiving information that are electronically beamed from a personal digital assistant ('136; Col. 26, lines 7-17).

38. With respect to Claim 24, the combined art teaches the method of claim 21, Inoue et al. discloses further comprising printing human readable information on the foldable and sealable packet ('247; Para 0108.)

39. With respect to Claim 25, the combined art teaches the method of claim 24, Chorosinski et al. discloses wherein the human readable information comprises at least one of a medication warning, drug recall information, batch number, lot number, patient

information, medication fill date, medication quantity, dosage, and directions for consumption ('651; Col. 5, lines 3-17.)

40. Claim 26 is rejected as the same reason with claim 21.

41. With respect to Claim 27, the combined art teaches the method of claim 26, Walsh discloses wherein the step of distributing the medication further comprises: reading a bar code image on a wrist band worn by the patient to extract wrist band information ('136; Col. 25, lines 10-15); reading a bar code image on the foldable and sealable packet to extract content information, the content information representing the contents of the foldable and sealable packet ('136; Col 25, lines 1-4, lines 16-17); comparing the wrist band information with the content information ('136; Col. 25, lines 18-19); providing the patient with the foldable and sealable packet containing the medication after confirming the wrist band information corresponds with the content information ('136, Col. 25, lines 19-26.)

Conclusion

42. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

43. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HIEP NGUYEN whose telephone number is (571) 270-5211. The examiner can normally be reached on Monday through Friday 7:30AM-5:00PM.

44. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

45. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/H. N./
Examiner, Art Unit 3686
December 30, 2008

/Gerald J. O'Connor/
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